

GOOD EARTH®

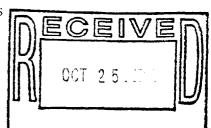
692 TOD MOVPRODUCTS



October 17, 2000

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)

Attn: Robert Moore
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204



RE: Notification Submitted Pursuant to DSHEA Section 6

Dear Mr. Moore:

Good Earth® submits this letter to satisfy the notification requirements established by Section 6 of the Dietary Supplement Health and Education Act of 1994 ("DSHEA") and 21 C.F.R. ' 101.93 for its Tea for Sleep^{tot} dietary supplement. The information in this notification is presented in the order set forth in 21 C.F.R. ' 101.93.

1. 101.93(a)(2)(i) - the name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement

The distributor of the dietary supplement is:

Good Earth® 831 Almar Avenue Santa Cruz, CA 95060

2. 101.93(a)(2)(ii) - the text of the statement that is being made

As permitted by Section 6 of the DSHEA and 21 C.F.R. ¹ 101.93(f), Tea for Sleep™ will bear the following, or substantially similar, claims:

- * "Relieves Occasional Sleeplessness"
- * "Tea for Sleep™ provides relief for occasional sleeplessness."
- * "Valerian root, Lemon Balm leaf, Hops flower, and Orange blossom are known for their calming action."

475-0162

73071 6121 Let

- * "For relief of restlessness and occasional sleeplessness due to simple nervous tension."
- 3. 101.93(a)(2)(iii) the name of the dietary ingredient or supplement that is the subject of the statement

The dietary ingredients in Tea for Sleep™ are Valerian root, Lemon Balm leaf, Hops flower, Orange blossom, Peppermint leaf, Lavender flower, and Rosemary leaf.

4. 101.93(a)(2)(iv) - the name of the dietary supplement (including brand name) on whose label, or in whose labeling, the statement appears

The supplement, "Tea for Sleep™," is marketed under the brand name "Good Earth® Medicinals™."

On behalf of Good Earth®, I certify that the information presented in this notification is complete and accurate. Further, Good Earth® possesses data substantiating that the statements identified in Paragraph 2 are truthful and not misleading.

If you have any questions concerning this notification, please contact me.

Craig Foster

Sincerely.

Research and Technical Sales Manager

Good Earth®